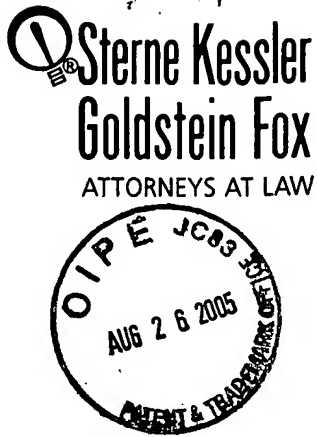


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August 26, 2005

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Commissioner for Patents,  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1645**

Re: U.S. Utility Patent Application  
Application No. 10/658,688; Filed: September 10, 2003  
For: **Codon-Optimized Polynucleotide-Based Vaccines Against *Bacillus anthracis* Infection**  
Inventor: Gary G. HERMANSON  
Our Ref: 1530.0460002/EJH/J-H

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement;
2. Form PTO-SB/08A, 1 page, listing 2 documents (US1 and US2);
3. Form PTO-SB/08B, 1 page, listing 4 documents (NPL1, NPL2, NPL3, and NPL4);
4. One (1) copy of the 3 cited documents (NPL1, NPL2, and NPL4); and
5. One (1) return postcard.

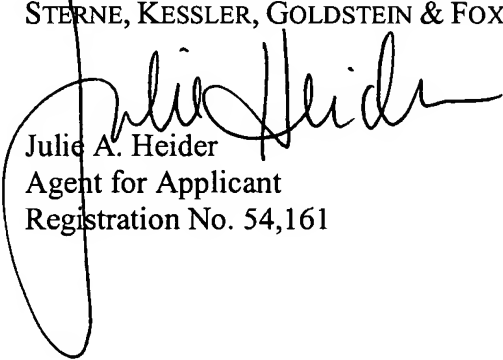
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
August 26, 2005  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Julie A. Heider  
Agent for Applicant  
Registration No. 54,161

EJH/J-H/tis  
Enclosures

425759v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary G. Hermanson

Appl. No.: 10/658,688

Filed: September 10, 2003

For: **Codon-Optimized Polynucleotide-  
Based Vaccines Against *Bacillus anthracis* Infection**



Confirmation No.: 3461

Art Unit: 1645

Examiner: Baskar, P.

Atty. Docket: 1530.0460002/EJH/J-H

**First Supplemental Information Disclosure Statement  
Filing Under Under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450  
Sir:

Listed on accompanying Form PTO-SB/08A and Form PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents **NPL1**, **NPL2**, and **NPL4** are submitted herewith. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of the U.S. patent and the U.S. patent application publication, documents **US1** and **US2**, cited on the attached Form PTO/SB/08A are not submitted.

In addition, a copy of document **NPL3** is not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is sua sponte waived where the cited pending application is stored in the USPTO's IFW system."

The Examiner's attention is directed to the following co-pending U.S. Patent Application, which is directed to related technical subject matter:

Application No. 10/843,656, inventors Vilalta, A., *et al.*, filed May 12, 2004, not yet published, cited herein as document **NPL3** on Form PTO/SB/08B.

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO/SB/08A and Form PTO/SB/08B based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not

Hermanson  
Appl. No. 10/658,688

exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

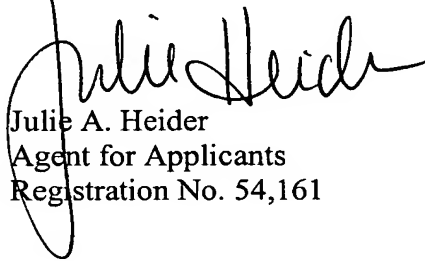
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return copies of the enclosed Form PTO/SB/08A and Form PTO/SB/08B, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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**FIRST SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet	1	of	1
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**Complete if Known**

Application Number	10/658,688
Filing Date	September 10, 2003
First Named Inventor	Gary Hermanson
Art Unit	1645
Examiner Name	Baskar, P.
Attorney Docket Number	1530.0460002/EJH/J-H

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

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Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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<b>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Complete if Known</b>	
				Application Number	10/658,688
				Filing Date	September 10, 2003
				First Named Inventor	Hermanson
				Art Unit	1645
Sheet	1	of	1	Examiner Name	Baskar, P.
				Attorney Docket Number	1530.0460002/EJH/J-H

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
	NPL1	Okinaka, R.T., <i>et al.</i> , "Sequence and Organization of pXO1, the Large <i>Bacillus anthracis</i> Plasmid Harboring the Anthrax Toxin Genes," <i>J. Bacteriol.</i> 181:6509-6515, American Society for Microbiology (1999)	
	NPL2	Price, L.B., <i>et al.</i> , "Genetic Diversity in the Protective Antigen Gene of <i>Bacillus anthracis</i> ," <i>J. Bacteriol.</i> 181:2358-2362, American Society for Microbiology (1999)	
	NPL3	Co-pending U.S. Patent Application No. 10/843,656, inventors Vilalta, A., <i>et al.</i> , filed May 12, 2004 (NOT PUBLISHED)	
	NPL4	Hermanson, G., <i>et al.</i> , "A Cationic Lipid-Formulated Plasmid DNA Vaccine Confers Sustained Antibody-Mediated Protection Against Aerosolized Anthrax Spores," <i>Proc. Natl. Acad. Sci. USA</i> 101:13601-13606, National Academy of Sciences (2004)	

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Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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